

Patent Claims

1. Liquid formulation which comprises human interferon- β as active ingredient in a concentration of up to 25 MU/ml and a buffer for setting a pH of 5 to 8, is free from human serum albumin and shows a long-term stability of the biological activity (in vitro) of at least 80% of the initial activity after storage for 3 months at 25°C.
2. Liquid formulation which comprises human interferon- β as active ingredient and a buffer for setting a pH of 6 to 7.2, is free from human serum albumin and shows a long-term stability of the biological activity (in vitro) of at least 80% of the initial activity after storage for 3 months at 25°C.
3. Liquid formulation which comprises human interferon- β as active ingredient, a buffer for setting a pH of 5 to 8, and one or more amino acids and shows a long-term stability of the biological activity (in vitro) of at least 80% of the initial activity after storage for 3 months at 25°C.
4. Formulation according to Claim 1, characterized in that it comprises a glycosylated interferon- β .
5. Formulation according to Claim 2, characterized in that the interferon- β originates from CHO cells.
6. Formulation according to ^{claim 1} ~~any of Claims 1 to 5,~~ characterized in that

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it comprises the buffer in a concentration of 10 mmol/l to 1 mol/l.

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C 7. Formulation according to ~~any of Claims 1 to 6,~~ *claim 1*
characterized in that
it comprises a buffer selected from the group consisting of phosphate, citrate and acetate buffers and mixtures of these.

10 8. Formulation according to Claim 7,
characterized in that
it comprises a phosphate/citrate buffer.

C 9. Formulation according to ~~any of Claims 1 and 3 to~~ *claim 1*
15 C ~~8,~~
characterized in that
it has a pH between 6 and 7.2.

10. Formulation according to Claim 3,
20 characterized in that
it is free from human serum albumin.

C 11. Formulation according to ~~any of Claims 1 to 10,~~ *claim 1*
characterized in that,
25 apart from the active ingredient, it is free from human or animal polypeptides.

C 12. Formulation according to ~~any of Claims 1 to 11,~~ *claim 1*
characterized in that
30 it is free from surfactants.

C 13. Formulation according to ~~any of Claims 1 to 12,~~ *claim 1*
characterized in that
it exhibits a chemical integrity after storage for
35 6 months at 25°C.

C 14. Formulation according to ~~any of Claims 1 to 13,~~ *claim 1*
characterized in that

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it exhibits a physical integrity after storage for 6 months at 25°C.

Sub 5
C 15. Formulation according to ^{claim 1} ~~any of Claims 1, 2 and 4 to 14,~~
5 C characterized in that
it furthermore comprises one or more amino acids.

C 16. Formulation according to Claim 3 ~~or 15,~~
10 characterized in that
it comprises methionine.

17. Formulation according to Claim 16,
characterized in that
15 the methionine is present in a concentration of
0.1 to 4 mmol/l.

C 18. Formulation according to ^{claim 1} ~~any of Claims 1 to 17,~~
20 characterized in that
it furthermore comprises auxiliaries for adjusting
the tonicity.

C 19. Formulation according to ^{claim 1} ~~any of Claims 1 to 18,~~
25 characterized in that
it furthermore comprises thickeners for increasing
the viscosity

C 20. Formulation according to ^{claim 1} ~~any of Claims 1 to 19,~~
30 characterized in that
it furthermore comprises physiologically
acceptable preservatives.

C 21. Pharmaceutical preparation,
characterized in that
35 C it comprises a liquid formulation according to ^{claim 1} ~~any~~
C ~~of Claims 1 to 20.~~
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22. Pharmaceutical preparation according to Claim 21 for oral, parenteral or ophthalmological administration.
- 5 C 23. Pharmaceutical preparation according to Claim 21
C ~~or 22~~ with unit doses of 1 to 25 MU.
- 10 24. Process for the preparation of a pharmaceutical preparation according to any of Claims 21 to 23, characterized in that a formulation according to any of Claims 1 to 20 and, if appropriate, other pharmaceutical formulation auxiliaries which are necessary is prepared and formulated as a suitable dosage form.
- 15 25. Process for improving the shelf life of a liquid formulation which comprises human interferon- β as active ingredient and a buffer for setting a pH of 5 to 8, characterized in that a formulation without human serum albumin or/and with one or more amino acids is used.
- 20 26. Process according to Claim 25, characterized in that the improved shelf life encompasses improved long-term stability of the biological activity (in vitro), of the chemical integrity or/and of the physical integrity.
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